

Collaborative Working Project Initiation Document:

Project Owner: Lisa Rosewarne – Local Access and Strategy Manager and Azar Ayoub – Field Access Manager

Partner Organisation: Walsall Healthcare NHS Trust

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A Collaborative Working Project between Grünenthal Limited (GL) and Walsall Healthcare NHS Trust (WHNHST).

1. Project Initiation Document	
Project title:	Optimising care for diabetic and neuropathic pain patients, and cancer-related neuropathic pain patients within the Black Country Integrated Care Board (ICB), and understand health inequalities that affect local underserved communities, through implementation of a dedicated pain optimisation service set within a specialist setting.
Project Overview:	<p>Walsall Healthcare NHS Trust (WHNHST) seek to work with Grünenthal Limited to pool experience, skills, and resources to maximise the opportunity to optimise care for the local positioned within Walsall Manor Hospital. The insights and outcomes gleaned through this project will inform a business case to the trust that articulates future service sustainability and builds a best practice exemplar for a new model of care for pain optimisation and service improvement which provides health inequality insights for future adoption across the NHS.</p> <p>The Black Country Integrated Care Board is an area of ethnic and cultural diversity where the needs and backgrounds of the local population are varied and multi-factorial. Walsall Healthcare NHS Trust and The Royal Wolverhampton Trust have outlined a joint strategy that centres around four strategic aims, referred to as the four C's. This strategy reflects their vision of delivering exceptional care together to benefit the communities they serve.</p> <ol style="list-style-type: none"> Care: Ensuring exceptional care delivery to improve community health and well-being. Collaboration: Strengthening the working relationship between the two trusts. Community: Prioritising community health and well-being. Colleagues: Attracting and supporting healthcare professionals to achieve these goals [1]. <p>The Black Country Integrated Care System (ICS) is committed to reducing health inequalities across health and social care in the Black Country. Their strategy emphasises addressing disparities and promoting health equity to enhance access, outcomes, and patient experience. Notably, the ICS has expanded their focus by including diabetes as a Core 6 area, alongside the existing Core 5 priorities. This strategic approach aims to improve the well-being of the communities they serve [2].</p>
Background:	<p>The local burden of diabetes in the black country exceeds the national average. Approximately 9 in 10 cases are deemed preventable, emphasising the importance of promoting an active lifestyle. Diabetic complications, such as cardiovascular, kidney, foot, and eye diseases, significantly impact residents' health and well-being. Early detection and effective management are crucial to reduce the risk of complications [3]. Cancer-related neuropathic pain can stem from the disease itself or caused by some cancer treatments. Chemotherapy-induced peripheral neuropathy affects a significant proportion of patients. Whilst advancements in cancer therapies have improved survival rates, managing side effects, especially neuropathy, remains a challenge. A thorough assessment is deemed crucial, ensuring timely intervention to address the neuropathic pain underlying cause. The patients in this cohort tend to be elderly with comorbidities present, which in turn creates the need for careful treatment decisions and appropriate review [4]. The Black Country ICB local population faces significant disparities, including lower life expectancy and higher deprivation rates. Nearly half of the population resides in the most deprived quintiles. Ethnic minority communities experience preventable illness-related mortality, linked to both ethnicity and deprivation. Additionally, unemployment rates, particularly among mixed ethnic populations, exceeds the national average. This mix of challenges present opportunities for future healthcare provision improvement and new models of service delivery that address local unmet needs, which is further fortified by the prevailing army of challenges the NHS faces of insufficient funding, staff shortages, a backlog of patients caused by COVID-19 pandemic, an increasingly ageing population and evolving healthcare needs [5].</p>

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	<p>Diabetes affects approximately 61.4 million people across Europe [6]. This carries a significant burden of diabetic nerve pain. Painful diabetic neuropathy profoundly impacts the quality of life for those living with diabetes. As such mitigating neuropathic pain emerges as a key objective. The project aims to reduce pain levels in this patient group through evidence-based interventions, fostering improved outcomes and enhancing well-being [7], [8]. Cancer-related neuropathy is a distressing consequence of malignancy and its treatments which significantly impacts patients' lives [9], [10]. The project aims to alleviate pain in this vulnerable group. By implementing evidence-based interventions, this initiative seeks to improve pain management outcomes, enhance quality of life, and empower cancer patients on their journey.</p> <p>These challenges underscore the need for innovative models of care and service delivery that meet the needs of the diverse local populations. Through addressing these unmet needs, the project will seek to improve population health outcomes, improve pathway efficiencies, improve time to treatment, and bridge gaps in healthcare provision to enhance well-being for the local Black Country population. Implementing the key project initiatives will provide enhanced neuropathic pain optimisation and care for local diabetic and neuropathic pain and, cancer-related neuropathic pain patient. The project initiatives will be supported by education, enhanced clinical capability, a healthcare professional neuropathic pain skills and confidence assessment program, piloting 5 local hubs to develop the framework to collect and evaluate the insights and outcomes. The project will collect insights, data, and learnings to inform a real-world understanding of local patients experience of care. The insights elicited through the project will support improvements in pain optimisation for both diabetes and cancer patients experiencing neuropathic pain with an enhanced focus on understanding existing health inequalities, supporting improvements in patient management, treatment, and outcomes for underserved local communities. The aims of the project align seamlessly with the WHNHST cost-improvement program by fostering integrated care and resource optimization, which are pivotal to both national and local priorities. Nationally, the NHS cost improvement program emphasizes reducing costs while enhancing patient care and safety [11]. Locally, the Black Country Integrated Care Board (ICB) prioritizes strategic healthcare planning and budget management to improve health outcomes for the community [1].</p> <p>This collaborative working project seeks to address this unmet provision through the design and implementation of 2 key service initiatives which include.</p> <ul style="list-style-type: none"> • Development of a pain optimisation service model as proof-of-concept/service improvement pilot 'best practice' example across Walsall Healthcare NHS Trust and the Black Country ICB locality. • Delivery of a business case to ensure pilot project incorporated into (WHNHST) and (BCICB) as exemplar pain optimisation pathway including the development of a blueprint for patient-focused service, in line with the local trust joint strategy [1] and local ICB priorities [2]. <p>The project will support 4 key service improvement initiatives which comprise:</p> <ol style="list-style-type: none"> 1.Optimising care for those living with diabetes and neuropathic pain and, cancer-related neuropathic pain. This will be undertaken via secondary care to primary care colleagues to virtually review, support clinical decision making, and, where necessary, see patients face to face. Grünenthal Limited will provide resources as documented in 'Parties Contribution: Figure A.' to support the service model throughout the duration of the project. 2. Increasing clinical capacity and capability of Walsall Healthcare NHS Trust to optimise pain management for patients who have been diagnosed with diabetes and neuropathy and/or cancer-related neuropathy, creating a 'care path' protocol for diabetes and neuropathy patients and cancer-related neuropathy patients. 3.Creating an educational package for healthcare professionals focusing on neuropathic pain management. This program will raise awareness and enhance healthcare professional understanding of neuropathic pain and, optimise inter and intra-centre experience to improve pain management practices. This initiative will provide practical tools to support the patient journey effectively. 4.Conducting in-depth assessments of the unique needs and challenges faced by local underserved populations within the diabetes and neuropathic pain and, cancer-related neuropathic pain contexts. These insights will inform targeted interventions to ensure equitable access to pain management resources and improved outcomes for patients. <p>The project will be delivered as a collaborative working initiative between WHNHST and Grünenthal Limited and co-ordinated through the diabetes team based at WHNHST to optimise neuropathic pain clinical care and the service-user experience for patients with diabetes and neuropathic pain, and cancer-related neuropathic pain. The new model of care that the project supports will introduce additional clinical sessions to further optimise and integrate neuropathic pain pathway development aligned to the local ICB priorities to improve outcomes in population health and health care, tackling inequalities in outcomes, experience and access and enhancing productivity and value.</p>
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Intended Aims and Objectives of the project:	<p>The overarching aim of the project is to optimise pain care for diabetes and neuropathy and, cancer-related neuropathic pain across the Black Country ICB and Walsall Healthcare NHS Trust locality and, understand existing health inequalities that pertain to diabetes and neuropathy, and cancer-related neuropathy patients in underserved communities within the local population. The project will focus on the following 5 objectives which will underpin the primary aim. Clarity and context pertaining to each objective is provided in Table 1. Project Outcomes. and Table 2. Project Actions. Table 1. Outlines the outcomes that are being collected through the project. Table 2. Outlines the actions of the co-parties to the project to achieve the objectives.</p> <p>Objective 1. Determine the impact and effectiveness of implementing a diabetes and neuropathy and, cancer-related neuropathic pain optimisation service across the Black Country ICB geography to optimise care and pain management for local patients and, understand existing health inequalities within these cohorts of patients pertaining to the local underserved communities.</p> <p>Objective 2. Support workforce development by devising and implementing a neuropathic pain confidence and skills assessment framework in line with national guidance for clinical staff to establish clinical need.</p> <p>Objective 3. To understand the local experiential learnings of the local healthcare professionals and clinical teams of deploying a diabetes and neuropathy and, cancer-related neuropathy related care service and local health inequalities initiative.</p> <p>Objective 4. To understand the experience of the diabetes and neuropathy and cancer-related neuropathy patient from detection, diagnosis, treatment and follow up at defined points in the patient pathway, cognisant of the local underserved populations.</p> <p>Objective 5. Development of a future diabetes and neuropathy and, cancer-related neuropathy related business case to support future deployment of optimal neuropathic pain care to the local healthcare system as a basis for future investment and sustainability.</p> <p>Outcomes must be published by all parties (NHS and Grünenthal Limited) as soon as possible and within 6 months of the project completion date.</p>				
Name of partner organisations :	<p>Walsall Healthcare NHS Trust Black Country Integrated Care board Grünenthal Limited</p>				
Name of representative for each organisation:	<p>Dr Senthil – Consultant Diabetologist, Walsall Healthcare NHS Trust Lisa Rosewarne – Local Access and Strategy Manager, UK/I, Grünenthal Limited Azar Ayoub – Field Access Manager – Grünenthal Limited Prish Kandaswamy – Head of Market Access, Grünenthal Limited</p>				
Expected Project Outcomes:	<table border="1"> <thead> <tr> <th data-bbox="284 1370 571 1406">Objective</th><th data-bbox="579 1370 1471 1406">Outcomes:</th></tr> </thead> <tbody> <tr> <td data-bbox="284 1417 571 2040"> Objective 1. Determine the impact and effectiveness of implementing a diabetes and neuropathy and, cancer-related neuropathy pain optimisation service across the Black Country ICB geography to optimise care and pain management for local patients and, understand existing health inequalities within these cohorts of patients pertaining to the local underserved communities. </td><td data-bbox="579 1417 1471 2040"> <p>1.An in-depth understanding of developing a neuropathic pain optimisation service and deployment of the service and in-depth analysis of the impacts and effectiveness of deployment of service objectives.</p> <ul style="list-style-type: none"> - Number of patients currently diagnosed at baseline - Number of predicted patients identified at baseline <p>Clinical Metrics:</p> <ul style="list-style-type: none"> - Assess pain severity using validated scales – NRS (11-point, NRS-3), LANSS Score - Functional improvement: Measure changes in daily activities, mobility, and sleep quality - Neurological Examination: Evaluate sensory and motor function. - Patient-reported outcomes: collect patient feedback on pain relief and overall well-being. - Discontinuation Rates: Track discontinuation rates through duration of project and track discontinuation insights - Specific symptom relief: Evaluate improvement in neuropathic pain symptoms. - Sub-group Analysis: Analyse outcomes for different neuropathy subtypes (e.g., diabetic, or cancer-related neuropathy) - Special occurrences before/during/after treatment: </td></tr> </tbody> </table>	Objective	Outcomes:	Objective 1. Determine the impact and effectiveness of implementing a diabetes and neuropathy and, cancer-related neuropathy pain optimisation service across the Black Country ICB geography to optimise care and pain management for local patients and, understand existing health inequalities within these cohorts of patients pertaining to the local underserved communities.	<p>1.An in-depth understanding of developing a neuropathic pain optimisation service and deployment of the service and in-depth analysis of the impacts and effectiveness of deployment of service objectives.</p> <ul style="list-style-type: none"> - Number of patients currently diagnosed at baseline - Number of predicted patients identified at baseline <p>Clinical Metrics:</p> <ul style="list-style-type: none"> - Assess pain severity using validated scales – NRS (11-point, NRS-3), LANSS Score - Functional improvement: Measure changes in daily activities, mobility, and sleep quality - Neurological Examination: Evaluate sensory and motor function. - Patient-reported outcomes: collect patient feedback on pain relief and overall well-being. - Discontinuation Rates: Track discontinuation rates through duration of project and track discontinuation insights - Specific symptom relief: Evaluate improvement in neuropathic pain symptoms. - Sub-group Analysis: Analyse outcomes for different neuropathy subtypes (e.g., diabetic, or cancer-related neuropathy) - Special occurrences before/during/after treatment:
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		<p>Service Metrics:</p> <ul style="list-style-type: none"> - Waiting Times: Monitor time from referral to consultation at baseline, 6 months, and 12 months - Treatment Adherence: Monitor patient compliance with prescribed interventions - Patient Satisfaction: Patient survey to elicit insights into patient experience with service. <p>Reduction in Pain Metrics:</p> <ul style="list-style-type: none"> - % reduction in pain scores: Baseline and follow-up pain scores - Responder rate: proportion of patients achieving clinically meaningful pain reduction. <p>Concomitant Medication Metrics:</p> <ul style="list-style-type: none"> - Medication changes: Document changes to existing pain medications - Reduction in analgesic use: Quantify changes in opioid, or other analgesic use. <p>Disease-Modifying Effects Metrics:</p> <ul style="list-style-type: none"> - HbA1c Levels: Monitor glycaemic control as it impacts neuropathy progression. - Blood Pressure Levels: Monitor at baseline, 6 months, and 12 months. - Cholesterol levels: Monitor at baseline, 6 months, and 12 months. <p>Quality of Life and Societal Value Metrics:</p> <ul style="list-style-type: none"> - Patient goal in relation to QOL/outcomes for improvement: - EQ-5D: Measure health-related quality of life - DASS-21: Measure changes in depression anxiety and stress values. - Norfolk Quality of Life – Diabetic Neuropathy (QOL-DN): Assess quality of life in diabetic polyneuropathy. - Productivity Gains: Estimate economic impact through reduced work absenteeism. <p>2. A secondary care to primary care educational package that supports virtual review, clinical decision making and patient consultation.</p> <p>3. A pathway map that visualises patient access flow for diabetes and neuropathic pain patients and cancer-related neuropathic pain patients. This map will be augmented with a full cost-analysis of the current and future state pathway and insights pertaining to health inequalities and access to care.</p> <p>4. Analysis of the impacts of:</p> <ul style="list-style-type: none"> - Implementing a pain optimisation service for diabetes and cancer patients with neuropathy programme of work - Implementation of local database intelligence to better understand current diagnostic pathways, access to treatment and healthcare outcomes for local underserved communities. <p>The above will be evaluated via questionnaires and focus group discussions by Walsall Healthcare NHS Trust. The subsequent qualitative analysis will be used to capture insights as appropriate to the project.</p> <p>5. Project management support provided by WHNHST to implement key project milestones.</p>
	<p>Objective 2: Support workforce development by devising and implementing a neuropathic pain confidence and skills assessment framework in line with national guidance for clinical staff to establish clinical need.</p>	<p>2. An in-depth understanding of the clinical aspects of diabetes and neuropathy and, cancer-related neuropathy to inform areas around clinical confidence and skills can be measured via a questionnaire.</p> <ul style="list-style-type: none"> ▪ Key aspects of diabetes and neuropathy and cancer-related neuropathy management identified. ▪ Clinical input to verify key areas and agree suitable questions to check confidence. ▪ Development of digital-based template to collate clinical HCP assessment of skills and confidence in neuropathic pain management in both diabetes and cancer-related management. ▪ Analysis and interpretation of data to identify workforce development areas. ▪ Local planning to agree on steps to deliver interventions to support workforce development.
	<p>Objective 3: To understand the local experiential learnings of the local healthcare professionals and clinical</p>	<p>1. Understand the current clinical practice and any variation within the local diabetes and neuropathy and cancer-related neuropathy clinical pathway at baseline that may influence the practical implementation of the project key initiatives.</p> <p>2. Qualitative and quantitative evaluation of the local HCP experience of implementing the key project initiatives across optimisation of care for the local patient living with</p>

	<p>teams of deploying a diabetes and neuropathy and, cancer-related neuropathy related optimum care and local health inequalities initiative.</p> <p>Objective 4: To understand the experience of the diabetes and neuropathy and cancer-related neuropathy patient from detection to diagnosis at defined points in the patient pathway, cognisant of the local underserved populations.</p> <p>Objective 5: Development of a future diabetes and neuropathy and, cancer-related neuropathy focused business case to support future deployment of optimal neuropathic pain care to the local healthcare system as a basis for future investment and/or sustainability.</p>	<p>diabetes and neuropathy and cancer-related neuropathy, with an enhanced focus on tackling local health inequalities.</p> <p>3. Understand perspective of local clinical and administrative staff on implementing the project initiatives.</p> <p>1. Qualitative and quantitative outputs and thematic analysis on the patient experience across the project care pathway.</p> <p>a. Patient experience of detection, diagnosis, and treatment at defined points in the pathway. This will be captured at diagnosis point of entry into the pathway, then at 6 months, then at month 12 of engagement with the pain optimisation pathway.</p> <p>b. Patients diagnosed being actively treated within the system.</p> <p>c. Patient Satisfaction: Patient survey to elicit insights into patient experience with service.</p> <p>2. Package feedback collected from patient perspectives to inform development of appropriate resources and/or approaches to support future patient activation and engagement with their care.</p> <p>1. Publication of a series of short articles on 'key learnings' at the end of the project (as soon as possible and within 6 months of project completion).</p> <p>2. Baseline needs assessment questionnaire to assess the starting levels of confidence, capacity, and skills to deliver diagnosis, treatment and optimisation of diabetes and neuropathy, and cancer-related neuropathy care.</p> <p>3. Development and publication of key learnings and best practice (may include algorithms, schematic pathways, and decision support tools, to mitigate against health inequalities).</p> <p>4. Development of a local business case to submit to WHNHST and local healthcare system for future investment and sustainability aligned to the trust cost improvement program [CIP].</p>
Key Actions/Initiatives:	Table 2. Project Actions:	
	<p>Objective:</p> <p>Objective 1. Determine the impact and effectiveness of implementing a diabetes and neuropathy and, cancer-related neuropathy pain optimisation service across the Black Country ICB geography to optimise care and pain management for local patients and, understand existing health inequalities within these cohorts of patients pertaining to the local underserved communities.</p> <p>Objective 2: Support workforce development by devising and implementing a neuropathic pain confidence and skills assessment framework in line with national guidance for clinical staff to establish clinical need.</p>	<p>Actions:</p> <p>1. WHNHST clinical team will develop the secondary care to primary care package and capture the quantitative and qualitative insights aligned to project key initiatives.</p> <p>2. WHNHST will establish the baseline number of identified diabetes and neuropathy patients, and cancer-related neuropathy patients and develop a hypothesis applicable to the trust and integrated care board (ICB) that estimates the likely impacts of implementing the project's key initiatives.</p> <p>3. WHNHST will identify, diagnose, and manage the management of patients identified as appropriate for neuropathic pain optimisation.</p> <p>4. The project group and supporting healthcare professionals will baseline the current diabetes and neuropathy pathway, and the cancer-related neuropathy pathway and map out the future state pathway(s) to encompass the project key initiatives as a schematic visual.</p> <p>1. The clinical lead and relevant supporting local healthcare professionals will review and agree relevant clinical aspects of diabetes and neuropathy, and cancer-related neuropathy relevant to primary care to access within a confidence and skills assessment framework.</p> <p>2. The clinical lead and relevant supporting local healthcare professionals supported by Grünenthal Limited Project Team will agree the questionnaires for deployment and use by the clinical team.</p> <p>3. The clinical lead and relevant supporting local healthcare professionals to ensure questionnaires are completed and Grünenthal Limited will help analyse the outputs to identify the local workforce development needs.</p>

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		4. The clinical lead to work with supporting local healthcare professionals to plan appropriate interventions to develop local workforce capability aligned to national clinical guidance.
	Objective 3: To understand the local experiential learnings of the local healthcare professionals and clinical teams of deploying a diabetes and neuropathy and, cancer-related neuropathy related optimum care and local health inequalities initiative.	1.WHNNHST will utilise the insights from the qualitative and quantitative analysis elicited through questionnaires, surveys, and thematic interviews, to ascertain the clinicians and administrative perspective of interacting with a diabetes and neuropathy and cancer-related neuropathy service based in a secondary care setting. 2.The clinical team and supporting local healthcare professionals will capture the diabetes and neuropathy and cancer-related neuropathy pathway pre and post the deployment of the future state service to assess the local confidence in diagnosis, treatment and follow up for these cohorts of patients. 3. All relevant NHS parties will capture data and insights pertaining to 'actual resource' impacts of diagnosis, treatment and follow up for patients identified through project initiatives.
	Objective 4: To understand the experience of the diabetes and neuropathy and cancer-related neuropathy patient from detection to diagnosis at defined points in the patient pathway, cognisant of the local underserved populations.	1. WHNNHST clinical team and supporting healthcare professionals to create relevant content and questionnaires to capture qualitative and quantitative insights aligned to project initiatives. 2. The clinical team will elicit the patient's understanding and perspectives one engagement with the project's key initiatives initiated through focus group activity and 1:1 interview. 3. The collaborative working project team will deploy a retrospective review of the average patient journey pre and post implementation of the key project initiatives supported through stakeholder workshop activity.
	Objective 5: Development of a future diabetes and neuropathy and, cancer-related neuropathy focused business case to support future deployment of optimal neuropathic pain care to the local healthcare system as a basis for future investment and/or sustainability.	1.WHNNHST to capture the 'real time' perspectives and learnings across participating integrated care board members in the project. 2. The collaborative working project team will curate an outcomes-based analysis of implementation of key project initiatives and outcomes, to be published within, or by 6 months of project completion. 3. The collaborative working project team will utilise an amalgamation of all the insights, learnings, and outcomes forthcoming from the project to develop future diabetes and neuropathy and, cancer-related neuropathy related care and health inequalities across the local geography.
Scope:	The scope of the project and the project initiatives therein, have been designed to provide direct improvements to the care and outcomes of patients at risk of, or being treated for the management of diabetes and neuropathy, and cancer-related neuropathic pain. These initiatives aim to address health inequalities that pertain to these patient groups, ensuring equitable access to pain optimisation strategies and enhance overall health outcomes and well-being.	

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Parties Contributions :	WHNHST will provide £11,284.92 of resourcing to support the project. The £11,284.92 is funding the following (see Figure A. below). Grünenthal Limited will provide £32,678.02 of resources. The Grünenthal Limited resources are funding the following, please refer to Figure B. <i>Figure A. Project Resource and Funding breakdown of contribution on Grünenthal Limited and Walsall Healthcare NHS Trust.</i>					
	Resource:	Hours per Month:	Time Ratio:	Value: £'s	WHNHST:	Grünenthal:
	Clinical Lead Consultant Diabetologist [12]	9.5 Hours @ £71.46 p/h	Clinic Time = 4 Prep Time = 5	£ 8,146.44 £ 678.87 p/m	£8,146.44	
	Senior Clinical Fellow [13]	9.5 Hours @ £37.52 p/h	Clinic Time = 4.5 Prep Time = 5	£ 4,277.28 £ 356.44 p/m		£4,277.28
	Nurse x 1 Band 7 WTE 0.25 [14]	9.5 Hours @ £27.53	Clinic Time = 4 Prep Time = 5	£12,131.50		12,131.50
	Podiatrist x 1 Band x 6-7	9.5 Hours @ £27.53	Clinic Time = 4 Prep Time = 5	£ 3,138.48 £ 261.54	£3,138.48	
	Project Manager Band 7	4 Hours @ £27.53	Project Steering Project Management and oversight	£1,321.44 £ 110.12		£1,321.44
	Project IT support Band 6	6 Hours @ £22.35	Ancillary Project support	£ 1,609.20 £ 134.10		£1,609.20
	Total:			£30,624.34	£11,284.92	£19,339.42
*Baseline salary costings are derived from the British Medical Association – Pay scales for consultants in England, 2023 and NHS Employers – Pay scales for 2024/25 [11, 12, 13.]. The final amounts in the value column are taken from a mid-range perspective. To achieve an hourly rate, the base salary is divided by 47 (52 – 5 weeks annual leave allocation) to give weekly rate, then divided by 5 for daily rate, then divided by 7.5 to achieve hourly rate. This hourly rate is then multiplied by the number of hours allocated to the project on a 47-week basis.						

	<p>Grünenthal Limited will provide £32,678.02 of funding and resources into the project to support project management, project facilitation, and ancillary project support (please refer to Figure B.). The below calculations have been derived from a Grünenthal Limited average daily rate of £454.73 divided by 7.5 to ascertain an hourly rate of £60.63, multiplied by the number of hours allocated to the project.</p> <p>Figure B. Grünenthal Limited contribution:</p> <table><tr><th>Resources and funding:</th><th>Value: £'s</th><th>Contribution Type:</th></tr><tr><td>Nurse Support Pain Optimisation services – Band 7 WTE 0.25</td><td>12,131.50</td><td>Funding</td></tr><tr><td>Senior Clinical Fellow Support</td><td>4,277.28</td><td>Funding</td></tr><tr><td>Project Manager Support</td><td>1,321.44</td><td>Funding</td></tr><tr><td>IT Support</td><td>1,609.20</td><td>Funding</td></tr><tr><td>Total Funding</td><td>19,339.42</td><td></td></tr><tr><td>Specialist input into project steering groups:</td><td></td><td></td></tr><tr><td>GRT Local Access and Strategy Manager (LASM)</td><td>20 hours</td><td>Resource</td></tr><tr><td>Field Access Manager (FAM)</td><td>15 hours</td><td>Resource</td></tr><tr><td>Medical Lead input</td><td>5 hours</td><td>Resource</td></tr><tr><td>Specialist input into Project Evaluation:</td><td></td><td></td></tr><tr><td>HEOR Oversight</td><td>10 hours</td><td>Resource</td></tr><tr><td>LASM support</td><td>30 hours</td><td>Resource</td></tr><tr><td>Specialist input into Operational Workstreams:</td><td></td><td></td></tr><tr><td>LASM</td><td>40 hours</td><td>Resource</td></tr><tr><td>FAM</td><td>100 hours</td><td>Resource</td></tr><tr><td>Total Resource Investment:</td><td>220 hours</td><td>Resource</td></tr><tr><td>Total Investment Value:</td><td>£13,338.60 + £19,339.42</td><td>Resource</td></tr><tr><td>Based on an hourly rate of: £60.63</td><td>£32,678.02</td><td></td></tr></table>	Resources and funding:	Value: £'s	Contribution Type:	Nurse Support Pain Optimisation services – Band 7 WTE 0.25	12,131.50	Funding	Senior Clinical Fellow Support	4,277.28	Funding	Project Manager Support	1,321.44	Funding	IT Support	1,609.20	Funding	Total Funding	19,339.42		Specialist input into project steering groups:			GRT Local Access and Strategy Manager (LASM)	20 hours	Resource	Field Access Manager (FAM)	15 hours	Resource	Medical Lead input	5 hours	Resource	Specialist input into Project Evaluation:			HEOR Oversight	10 hours	Resource	LASM support	30 hours	Resource	Specialist input into Operational Workstreams:			LASM	40 hours	Resource	FAM	100 hours	Resource	Total Resource Investment:	220 hours	Resource	Total Investment Value:	£13,338.60 + £19,339.42	Resource	Based on an hourly rate of: £60.63	£32,678.02	
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Arrangements and accountabilitys for longer term funding implications of project – sustainability plans:	<p>The insights, outputs, and outcomes derived from this project will shape a comprehensive business case to Trust. This business case will emphasise future sustainability, enhanced patient care, and improved patient outcomes. These insights will be triangulated with a focus on system efficiencies and delivering optimised care for local underserved communities to inform a long-term viability assessment and a greater understanding of impactful health improvements, aligned to the trust cost improvement program of work.</p>																																																									
Estimated start date of project: Start Date: Duration: Project Interval dates: Completion:	<p>The project is scheduled to commence in September 2025 and will span a duration of 12 months. Key interim milestones are set at 6 months from the project start date to ensure ongoing progress and alignment with project key initiatives and objectives. A comprehensive evaluation is planned at the 12-month stage to assess the project's overall impact and effectiveness and overall success. Date of completion is March 2027.</p>																																																									
Acceptance Criteria:	<p>The project will be deemed successful within the following tolerances:</p> <ul style="list-style-type: none">Project defined outcomes delivered > than or = to a minimum of 70% of the agreed project plan.Project is delivered within 2 months of the agreed timescales outlined within the project action plan.Project is delivered within 6 months of contract initiation.																																																									
Assumptions:	<p>The current healthcare landscape, including the local Integrated Care Board remains stable and resilient against potential health crises. The project will continue to monitor emerging health threats and infection rates through reliable data sources to ensure preparedness and adaptability.</p>																																																									

Collaborative Working Project Initiation Document:

Project Owner: Lisa Rosewarne – Local Access and Strategy Manager and Azar Ayoub – Field Access Manager

Partner Organisation: Walsall Healthcare NHS Trust

Adverse event and safety reporting:	<p>Walsall Healthcare NHS Trust staff will follow their internal policy/processes for capturing and reporting suspected adverse reactions identified during the project, as appropriate.</p> <p>The Medicines and Healthcare products Regulatory Agency (MHRA) requests healthcare professionals (HCPs) to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme. HCPs can report via:</p> <ul style="list-style-type: none"> - the Yellow Card website: www.mhra.gov.uk/yellowcard. - the free Yellow Card app available from the Apple App Store or Google Play Store. - some clinical IT systems (EMIS/SystemOne/Vision/MiDatabank) for healthcare professionals. <p>Alternatively, a suspected adverse drug reaction can be reported to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm. HCPs can leave a message outside of these hours. When reporting, HCPs are asked to provide as much information as possible.</p> <p>Grünenthal Limited will not participate in initiatives that involve direct data collection or engagement with patients. In the event Grünenthal Limited is made aware of the data collected by Walsall Healthcare NHS Trust containing safety information with Grünenthal Limited's medicines(s), this will be considered as secondary use of data at Grünenthal Limited.</p>
Exit Strategy:	<p>If any collaborative working party wishes to withdraw from the collaborative working agreement, the party must provide one month's written notice to the other party, to notify of intent to withdraw with clear documentation of the reason for withdrawing.</p> <ul style="list-style-type: none"> ▪ Lack of patient benefit requires both parties to withdraw and any evidence of patient detriment, must result in immediate termination of the project. ▪ The parties to this agreement are cognisant that Grünenthal Limited is required to comply with the ABPI code of practice. Accordingly, if any action of the parties is deemed to be in breach of the code, the collaborative working agreement will terminate with immediate effect. ▪ In the event of early termination of the collaborative working agreement, the costs to that point will be agreed and any outstanding matters resolved regarding the return of unspent resource. <p>The collaborative working agreement will terminate with immediate effect if a collaborative working party commits a material breach of this agreement and fails to remedy it within 10 working days of being informed of the breach by the other party (for example, a party fails to honour their obligations under the auspices of this collaborative working agreement, or fails to pay their relevant part of resources or funding), or engages in corrupt practices.</p>
Project Controls:	<p>The collaborative working project group will meet on a 6 weekly basis up to the initial 11 months of the project, followed by one final meeting to consult on the evaluation and will report into:</p> <ul style="list-style-type: none"> - Walsall Healthcare NHS Trust - Grünenthal Limited Senior Leadership Team. <p>Operational task and finish groups will be convened to deliver the specific initiatives within the project. These will report into the Project Steering Group.</p>

2. Project Organisation and Structure

P2. Governance Arrangements																																																																																																															
Which stakeholders will be consulted prior to initiating CW/JW project and how will this consultation be conducted:	<table border="1"> <tr> <td colspan="8">Grünenthal Limited</td> </tr> <tr> <td colspan="4">Name:</td> <td colspan="4">Role:</td> </tr> <tr> <td colspan="4">Bonita Ho-Asjoe</td> <td colspan="4">Business Unit Director – (Growth UK, Ireland)</td> </tr> <tr> <td colspan="4">Prish Kandaswamy</td> <td colspan="4">Head of Market Access</td> </tr> <tr> <td colspan="4">Melinda Setanoians</td> <td colspan="4">Head of Medical UKINOR Cluster</td> </tr> <tr> <td colspan="4">Lisa Rosewarne</td> <td colspan="4">Local Access and Strategy Lead</td> </tr> <tr> <td colspan="4">Azar Ayoub</td> <td colspan="4">Field Access Manager</td> </tr> <tr> <td colspan="8">Walsall Healthcare NHS Trust</td> </tr> <tr> <td colspan="4">Name:</td> <td colspan="4">Role:</td> </tr> <tr> <td colspan="4">Dr Senthil</td> <td colspan="4">Consultant</td> </tr> <tr> <td colspan="4">Tracy Crutchley</td> <td colspan="4">Business Manager</td> </tr> <tr> <td colspan="4">Rabeena Narwain</td> <td colspan="4">Deputy Divisional Director</td> </tr> <tr> <td colspan="4">Will Roberts</td> <td colspan="4">Chief Operating Officer</td> </tr> </table>							Grünenthal Limited								Name:				Role:				Bonita Ho-Asjoe				Business Unit Director – (Growth UK, Ireland)				Prish Kandaswamy				Head of Market Access				Melinda Setanoians				Head of Medical UKINOR Cluster				Lisa Rosewarne				Local Access and Strategy Lead				Azar Ayoub				Field Access Manager				Walsall Healthcare NHS Trust								Name:				Role:				Dr Senthil				Consultant				Tracy Crutchley				Business Manager				Rabeena Narwain				Deputy Divisional Director				Will Roberts				Chief Operating Officer			
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Project Governance:	<p>The Project Steering Committee will provide strategic oversight and direction for the project. This committee will include senior representatives from both our organisation and the NHS, ensuring alignment with both parties' goals and objectives.</p> <p>Roles and Responsibilities:</p> <p>Project Lead: Provides overall project sponsorship and ensures alignment with strategic objectives:</p>																																																																																																														

Collaborative Working Project Initiation Document:

Project Owner: Lisa Rosewarne – Local Access and Strategy Manager and Azar Ayoub – Field Access Manager

Partner Organisation: Walsall Healthcare NHS Trust

	<p>Project Manager: Manages day-to-day operations, coordinates activities, and ensures project milestones are met.</p> <p>Clinical Leads: Provide clinical expertise and ensure the model care meets clinical standards.</p> <p>Field Access Manager: Act as primary liaison between Grünenthal Limited and the NHS, facilitating communication and collaboration.</p> <p>Health Inequalities Lead: Ensures the project addresses health inequalities and promotes equitable care.</p> <p>Decision-Making Process:</p> <p>Decisions will be made collaboratively, will input from all key stakeholders. Major decisions will be escalated to the Project Steering Committee for approval. Regular meetings will be held to review progress, address challenges, and make necessary adjustments.</p>																																																								
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Project Plan:	<p>The project will be delivered in accordance with the draft timeline GANNT chart listed below (see Figure C.) <i>Figure C. Draft Project Plan (September 24 – March 26)</i></p> <table><tr><th>Description (Owner):</th><th>Start Date:</th><th>Completion:</th></tr><tr><td>Project sign off/completion</td><td>June 24</td><td>September 25</td></tr><tr><td>WHNHST project sign off</td><td>September 25</td><td>September 25</td></tr><tr><td>Project Manager develop detailed project plan</td><td>Sept/Oct 25</td><td>Sept/Oct 25</td></tr><tr><td>Implement project initiatives</td><td>Sept/Oct 25</td><td>Sept/Oct 25</td></tr><tr><td>Map current clinical practice (WHNHST) and project group – workshop 1.</td><td>October 25</td><td>October 25</td></tr><tr><td>Engage with BCICB/WHNHST services and staff</td><td>Sept/Oct 25</td><td>Sept/Oct 25</td></tr><tr><td>Establish baseline data (clinical) (joint)</td><td>Sept/Oct 25</td><td>Sept/Oct 25</td></tr><tr><td>Understand unmet needs</td><td>Sept/Oct 25</td><td>Sept/Oct 25</td></tr><tr><td>Understand current clinical pathway, identify barriers</td><td>Oct/Nov 25</td><td>Oct/Nov 25</td></tr><tr><td>Understand the differences in diagnostic pathway, access to healthcare and healthcare outcomes for local underserved communities.</td><td>Oct/Nov 25</td><td>Oct/Nov 25</td></tr><tr><td>Neuropathic pain skills and confidence assessment framework – questionnaire building and digitalisation.</td><td>Oct/Nov 25</td><td>Oct/Nov 25</td></tr><tr><td>Neuropathic pain skills assessment and confidence mapping baseline assessment</td><td>Oct/Nov 25</td><td>Oct/Nov 25</td></tr><tr><td>Establish baseline data staff views and experiential insights re: diabetes and neuropathy and cancer-related pain optimisation, and health inequalities initiative.</td><td>Oct/Nov 25</td><td>Oct/Nov 25</td></tr><tr><td>6-month stakeholder workshop 2 – to consolidate progress and identify next steps</td><td>March/April 26</td><td>March/April 26</td></tr><tr><td>12- month stakeholder workshop 3 – to consolidate progress of the project</td><td>September 26</td><td>September 26</td></tr><tr><td>Neuropathic pain skills and assessment recommendations</td><td>September 26</td><td>September 26</td></tr><tr><td>Evaluation of best practice and sustainability</td><td>March 27</td><td>March 27</td></tr></table>			Description (Owner):	Start Date:	Completion:	Project sign off/completion	June 24	September 25	WHNHST project sign off	September 25	September 25	Project Manager develop detailed project plan	Sept/Oct 25	Sept/Oct 25	Implement project initiatives	Sept/Oct 25	Sept/Oct 25	Map current clinical practice (WHNHST) and project group – workshop 1.	October 25	October 25	Engage with BCICB/WHNHST services and staff	Sept/Oct 25	Sept/Oct 25	Establish baseline data (clinical) (joint)	Sept/Oct 25	Sept/Oct 25	Understand unmet needs	Sept/Oct 25	Sept/Oct 25	Understand current clinical pathway, identify barriers	Oct/Nov 25	Oct/Nov 25	Understand the differences in diagnostic pathway, access to healthcare and healthcare outcomes for local underserved communities.	Oct/Nov 25	Oct/Nov 25	Neuropathic pain skills and confidence assessment framework – questionnaire building and digitalisation.	Oct/Nov 25	Oct/Nov 25	Neuropathic pain skills assessment and confidence mapping baseline assessment	Oct/Nov 25	Oct/Nov 25	Establish baseline data staff views and experiential insights re: diabetes and neuropathy and cancer-related pain optimisation, and health inequalities initiative.	Oct/Nov 25	Oct/Nov 25	6-month stakeholder workshop 2 – to consolidate progress and identify next steps	March/April 26	March/April 26	12- month stakeholder workshop 3 – to consolidate progress of the project	September 26	September 26	Neuropathic pain skills and assessment recommendations	September 26	September 26	Evaluation of best practice and sustainability	March 27	March 27
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Resources and Costs:	
Arrangements for longer terms funding implications of project:	The insights, outputs and outcomes of this project are expected to inform a future business case to the local Health Trust to highlight the sustainability, impact, effectiveness, and value of the service. These insights will support future in-house investment decisions.
3.Data and Patient Protection:	
Ownership of data generated by the project:	<p>All data generated by the project will be owned jointly by the parties.</p> <ul style="list-style-type: none"> ▪ No data will be disclosed to any third party except on the explicit agreement of all parties. ▪ Patient confidentiality will be maintained at all times, and Grünenthal Limited shall not be entitled to see or review individual patient data, and the Trust and NHS will take the necessary steps and implement the necessary security parameters to prevent this from occurring. ▪ All existing background intellectual property rights used in connection with the Project, and which are derived from existing intellectual property rights of one of the parties shall remain the property of the inventing party ("Background IP"). ▪ Excluding Grünenthal Limited Background IP, the Trust acknowledges and agrees that all intellectual property in any other tools and materials created under the Project shall be jointly owned by the parties, save that the parties agree to grant the Trust a perpetual royalty-free non-exclusive licence to use such intellectual property for the purposes of patient care. ▪ The parties to this Collaborative Working Agreement may use and disclose know-how and other information gained through the Project in connection with other joint working projects provided always that the industry parties agree not to use any of the Trust's confidential information on such projects and vice versa.

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**P3.
Monitoring
and
Evaluation:**

**Final review
date and
expected
learning
outcomes
from this
project:**

The final review date is 18 months from project start date. Expected review completion date: March 2027.